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VIDAS, ARRETT & STEINKRAUS, P.A.
SUITE 400, 6640 SHADY OAK ROAD
EDEN PRAIRIE, MN 55344

EXAMINER	
WITCZAK, CATHERINE	

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/645,653
Filing Date: August 20, 2003
Appellant(s): FREYMAN ET AL.

Lisa R. Lindquist
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed 11/25/2008 appealing from the Office action mailed 5/28/2008.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5,713,853	CLARK et al	2-1998
6,364,856	DING et al	4-2002

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claims 25-40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clark et al (US 5,713,853) as modified by Ding et al (US 6,364,856).

Claims 24, 25, 26, 27, and 40: Clark et al disclose in Figures 24-26 a medical device comprising a shaft (702); an initially cylindrically shaped delivery member (706); a therapeutic agent delivery lumen (710) connected to a therapeutic agent source; a retention member (704); and a therapeutic agent source being a syringe which is capable of applying negative pressure.

Clark et al disclose the claimed invention except for the delivery member being shaped in a continuous solid cylindrical configuration. Ding et al teach in Figures 2 and 3 that it is known to use a delivery member having a continuous solid cylindrical shape. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Clark et al with a continuously solid delivery member, since such a structure would ensure maximum contact with the treatment area when the delivery member is in its expanded state.

Claims 28 and 29: Clark et al disclose in column 7, line 18-column 8, line 47 the delivery member being formed of a porous, degradable material.

Claims 30 and 31: Clark et al disclose in Figure 24 the delivery member configured to conform to the internal contour of the target body lumen when expanded.

Claims 32, 33, 34 and 35: Clark et al disclose in Figure 25 the proximal and distal ends of the delivery member being tapered end caps.

Claim 36: Clark et al disclose in column 14, line 2-4 the delivery member having a length between 5mm and 40 mm.

Claims 37, 38 and 39: Clark et al disclose in Figure 25 the shaft having a wire lumen for receiving a guidewire which extends into the delivery member.

(10) Response to Argument

In response to Appellant's argument that Ding et al do not disclose a balloon being shaped in a solid cylindrical configuration, Examiner points to Figures 1b, 3 and 4b in which Ding et al disclose a balloon having, in its center section, a solid cylindrical configuration. Although the ends of the balloons in Ding et al's figures may be tapered, Examiner points out that there is no limitation in the claim that requires the entire length of the balloon to be a solid cylindrical configuration, and that furthermore Appellant themselves disclose in their figures that only middle portion (18) is cylindrical while distal and proximal ends (54 and 50) are tapered. Clearly Ding et al. teaches the use of a porous material as noted by appellant on pages 11 and 12 of the appeal brief.

In response to Appellant's argument that there is no suggestion to combine the references, the examiner recognizes that obviousness can only be established by combining or modifying the teachings of

the prior art to produce the claimed invention where there is some teaching, suggestion, or motivation to do so found either in the references themselves or in the knowledge generally available to one of ordinary skill in the art. See *In re Fine*, 837 F.2d 1071, 5 USPQ2d 1596 (Fed. Cir. 1988)and *In re Jones*, 958 F.2d 347, 21 USPQ2d 1941 (Fed. Cir. 1992). In this case, it would have been obvious to combine the references of Clark and Ding, because it is the shaft structure in combination with a therapeutic agent delivery lumen, initially cylindrically shaped delivery member, therapeutic agent source, retention member, and syringe of Clark that one of ordinary skill in the art would be looking to combine with Ding's device NOT the delivery member itself of Clark's device. The Clark reference is used to teach that such a system is known to advance delivery member to an internal portion of a patient's body, and thus it would be obvious to put the continuous solid cylindrical delivery member of Ding on Clark's device, regardless of the fact that the device Clark uses is not a continuous solid cylindrical delivery member. It is the Examiner's position that besides disclosing a system comprising a delivery member with spaced ribs which are intended to allow the device to serve as a thrombolytic filter or which allow the device to deliver drugs to a vessel without blocking blood flow, Clark discloses a second system, as described in column 3, lines 56-60: "a method of delivering drugs or other agents to a lumen ... comprising advancing a catheter having compressed delivery members, releasing the delivery members, and delivering drugs or other agents through the catheter and delivery members." It is this second system (not the first as argued by the Appellant) that the Examiner is relying on for the basis of the obviousness rejection. The second system makes no reference of the delivery member functioning to serve as a filter or to allow blood to flow through when expanded; instead this second system of Clark is simply drawn to a method of positioning a drug releasing expandable member within a lumen. It is the Examiner's position that it would be obvious to modify this system with a delivery member as taught by Ding. Although Ding does not explicitly state why a solid cylindrical shape is used from the device, Ding discloses in column 4, lines 3-6 that "additional expansion of the balloon causes the drug, which is in the sponge coating to be

released from the sponge coating into the afflicted tissue." As would be obvious to one having ordinary skill in the art at the time the invention was made, the larger the surface area of the balloon, the greater the contact surface with the tissue and thus more drug is released to the tissue. For these reasons, it is the Examiner's position that it would be obvious to modify Clark's method of positioning a delivery device within a lumen with a solid cylindrical balloon as taught by Ding since such a modification would provide for an easily positionable member which efficiently disperses drugs to the surrounding lumen.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Catherine N Witczak/

Examiner, Art Unit 3767

Conferees:

/Kevin C. Sirmons/

Supervisory Patent Examiner, Art Unit 3767

/Janet C. Baxter/
TC 3700 TQAS